DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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00P-0596/CP1

Robert D. Gunderson
Phoenix Scientific, Inc.
3915 S. 48th St. Terrace
P.O. Box 8039 (64508)
St. Joseph, MO 64503

Dear Mr. Gunderson:

We refer to your Suitability Petition filed February 14, 2000, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product that differs in dosage form from that of an approved new animal drug. The proposed pioneer product is Phoenix Scientific Inc.'s Phenylbutazone Tablets USP, 1 gram, for use in horses (NADA 91-818), and the proposed generic product is phenylbutazone granular powder.

As we discussed with you, since Phoenix Scientific, Inc. is the owner of the pioneer NADA, you already have access to information that can be used for the new dosage form. You need only incorporate it by reference into a new NADA seeking approval for the requested new dosage form. Therefore, your suitability petition requesting permission to submit an ANADA for a generic copy of your own product is unnecessary

We refer you to Dr. Melanie Berson, Director, Division of Therapeutic Drugs for Non-Food Animals, (301) 827-7540, for any questions you may have regarding study requirements for a new NADA. Further correspondence regarding this subject may be addressed to CVM's Document Control Unit, HFV-199, with reference to your approved application, NADA 91-818.

Sincerely yours,

Claire M. Lathers

Claire M. Lathers, Ph.D., F.C.P.
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

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